

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

**LINA COLE, on behalf of herself and her
eleven-year-old daughter A.C.; MELISSA
GOLPL, on behalf of herself and her fifteen-year-
old son P.K.; DENISE RANDELLO, on behalf of
herself and her thirteen-year-old daughter A.R.;
LISA BOYLE MEYER, on behalf of herself and
her sixteen-year-old daughter K.M.; and TOBY
DOELL-CARBONE, on behalf of herself and her
eleven-year-old twins M.C. and J.C.,**

Plaintiffs,

v.

**1:17-CV-251
(FJS/CFH)**

**HOWARD ZUCKER, in his official capacity as the
Commissioner of the New York State Department
of Health,**

Defendant.

APPEARANCES

OF COUNSEL

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SCULLIN, Senior Judge

MEMORANDUM-DECISION AND ORDER

I. INTRODUCTION

In their complaint, Plaintiffs, all of whom are parents of children between the ages of eleven

and sixteen, allege that they commenced this action against Defendant in his official capacity "to challenge the validity of the No Consent or Knowledge Rule[, 10 N.Y.C.R.R. § 23.4,] to the extent it permits health care practitioners in New York State to inject Gardasil or Gardasil-9 manufactured by Merck & Co., Inc., into children without parental consent or knowledge." *See* Dkt. No. 1, Complaint, at ¶¶ 4, 8.¹ Plaintiffs assert two bases for their action: (1) "the No Consent or Knowledge Rule is invalid because 42 U.S.C. § 300aa-26, part of the National Childhood Vaccine Injury Act, requires that *before* a child is injected with any vaccine, such as Gardasil or Gardasil-9, the parent or legal guardian of such child must be provided the Vaccine Information Statement created by the Center for Disease Control for the specific vaccine"; and (2) "enforcement of the No Consent Or Knowledge Rule is unconstitutional because it violates the Fourteenth Amendment of the United States Constitution, and enforcement is unlawful for that separate and distinct reason." *See id.* at ¶¶ 5-6. Thus, Plaintiffs "seek[] a declaration of the invalidity of the No Consent Or Knowledge Rule and a permanent injunction enjoining enforcement of this rule." *See id.* at ¶ 7.

In their complaint, Plaintiffs assert three causes of action pursuant to 42 U.S.C. § 1983: (1) "deprivation of rights and privileges secured by federal law"; (2) "deprivation of rights and privileges secured by the Constitution [-] Procedural Due Process"; and (3) "deprivation of rights and privileges secured by the Constitution [-] Substantive Due Process." *See generally* Complaint.

Defendant has moved to dismiss Plaintiffs' complaint pursuant to Rule 12(b)(1) and Rule 12(b)(6) of the Federal Rules of Civil Procedure. *See* Dkt. No. 8. Plaintiffs oppose this motion. *See* Dkt. No. 9.

¹ One of the Plaintiffs, Lisa Boyle Meyer, is the mother of a sixteen-year-old daughter who "has been severely injured by an HPV [Human Papillomavirus] vaccine." *See* Complaint at ¶ 12. The other Plaintiffs do not indicate whether their children have received such a vaccine.

II. BACKGROUND

In May 2016, the New York Department of Health, through Defendant, its Commissioner, promulgated a new regulation that allows health care practitioners to administer HPV vaccines, such as Gardasil or Gardasil-9, to minor children without their parents' consent or knowledge. *See* Complaint at ¶ 2. That regulation, codified in 10 NYCRR § 23.4, provides as follows:

When a health care provider diagnoses, treats or prescribes for a minor, without the consent or knowledge of a parent or guardian as permitted by section 2305 of the Public Health Law, neither medical nor billing records shall be released or in any manner be made available to the parent or guardian of such minor without the minor patient's permission. In addition to being authorized in accordance with section 2305 of the Public Health Law to diagnose, treat or prescribe for a person under the age of eighteen years without the consent or knowledge of the parent or guardian of such person where the individual is infected with a sexually transmitted disease, or has been exposed to infection with a sexually transmitted disease, health care practitioners may (as authorized by their scope of practice) render medical care related to other sexually transmitted diseases without the consent or knowledge of the parent or guardian.

10 N.Y.C.R.R. § 23.4.

Under § 2305 of New York Public Health Law, "[a] licensed physician . . . may diagnose, treat or prescribe for a person under the age of twenty-one years without the consent or knowledge of the parents or guardian of said person, where such person is infected with a sexually transmitted disease, or has been exposed to infection with a sexually transmitted disease." N.Y. Pub. Health Law § 2305(2). Section 23.4 broadens the scope of § 2305 by permitting health care practitioners to "render medical care related to other sexually transmitted diseases [("STD"s)]" to minors even if they have not been infected with or exposed to an STD infection. Therefore, pursuant to § 23.4, health care practitioners may provide medical treatment related to STD prevention, such as administering a vaccine to protect against an STD such as the Human Papilloma Virus ("HPV"), to

minors without the consent or knowledge of their parents.

The Department of Health enacted § 23.4, in part, to guard against HPV, a commonly transmitted STD. Currently, the only available vaccination against HPV is Gardasil or Gardasil-9 (collectively "the HPV vaccine"), which protects against certain strains of the virus, including those that have been linked to cancer. *See* Complaint at ¶¶ 1-2, 17-18. The HPV vaccine may not protect against the virus if a patient has already been sexually active and, therefore, potentially exposed to the virus. *See id.* at ¶ 21. Thus, the manufacturers of the HPV vaccine recommend that health care practitioners administer it before a patient is sexually active, *i.e.*, to patients between the ages of 11 and 12 years old, although children as young as 9 years old and older patients who have not yet contracted the virus may also receive the vaccine. *See id.*

The HPV vaccine is a covered vaccine within the meaning of the National Childhood Vaccine Injury Act ("NCVIA"), and therefore health care practitioners must provide a child's legal representative with certain written materials prior to injecting the child with that vaccine. *See* 42 U.S.C. § 300aa-26. Specifically, under § 300aa-26(d) of the NCVIA, entitled, "Health care provider duties,"

each health care provider who administers a vaccine set forth in the Vaccine Injury Table [("VIT")] shall provide to the legal representative of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

42 U.S.C. § 300aa-26(d).

Pursuant to subsection (a) of § 300aa-26, the Secretary of Health and Human Services ("HHS") "shall develop and disseminate vaccine information materials for distribution by health care

providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table." 42 U.S.C. § 300aa-26(a). To that end, the Secretary of HHS has developed a "Vaccine Information Statement" ("VIS") for each VIT-covered vaccine, including the HPV vaccine. *See* Final Revised Vaccine Information Materials for 9-valent HPV (Human Papillomavirus) Vaccine, 81 Fed. Reg. 232299-01 (Apr. 20, 2016); *see* <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv.html> (last visited January 25, 2019).

Thus, pursuant to § 300aa-26, health care practitioners must provide parents with an "HPV vaccine VIS" prior to administering the HPV vaccine to their children.

Plaintiffs allege that § 23.4 interferes with their constitutional right under the Fourteenth Amendment to participate in and make medical decisions on behalf of their children because, they claim, the statute prevents health care practitioners from informing parents of their children's decision to receive the HPV vaccine unless their children consent. *See* Plaintiffs' Memorandum of Law at 15; 10 N.Y.C.R.R. § 23.4. Plaintiffs also assert that § 23.4 prohibits health care practitioners from releasing pertinent medical information, such as the HPV vaccine VIS, to parents without the minor patient's permission, which also deprives them of their constitutional rights.

In addition, Plaintiffs contend that § 23.4 directly conflicts with federal law, in particular the VIS Rule under the NCVIA, which requires health care practitioners to provide parents with an NCVIA-covered vaccine's VIS, including the HPV vaccine, prior to inoculating their children and, by doing so, "deprives parents . . . of vital knowledge about the vaccine that [the VIS Rule] requires the parent to receive" before health care practitioners administer the vaccine, such as (1) the adverse side effects of the vaccine and (2) if their child has previously received the vaccine. *See* Plaintiffs' Memorandum of Law at 22, 24.

III. DISCUSSION

A. Standard of review

At the commencement of a case, federal courts are "'duty bound' . . . to address the issue of subject matter jurisdiction" *Brickey v. Superintendent, Franklin Corr. Facility*, Civ. No. 9:10-CV-085, 2011 WL 868148, *3 (N.D.N.Y. Feb. 17, 2011) (quoting *Filetech S.A. v. France Telecom S.A.*, 157 F.3d 922, 929 (2d Cir. 1988)). "A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000) (citing Fed. R. Civ. P. 12(b)(1)).

In assessing a motion to dismiss under Rule 12(b)(1), courts must "accept as true all material factual allegations in the complaint" but should not draw "argumentative inferences favorable to the party asserting jurisdiction" *Atl. Mut. Ins. Co. v. Balfour MacLaine Int'l Ltd.*, 968 F.2d 196, 198 (2d Cir. 1992) (citations omitted). Courts may also "look to evidence outside the pleadings" and must resolve "all ambiguities . . . and . . . [draw all reasonable inferences] in favor of the plaintiff." *Kinsey v. Charitable Leadership Found.*, No. 11-CV-0602, 2012 WL 1014808, *2 (N.D.N.Y. Mar. 23, 2012) (citations omitted). The plaintiff "must prov[e] subject-matter jurisdiction by a preponderance of the evidence." *Id.* (citation omitted).

Finally, one element of subject matter jurisdiction is standing. Thus, dismissal under Rule 12(b)(1) is proper if a court finds that the plaintiff has failed to establish standing to assert her claim. *See Wademan v. Concra*, 13 F. Supp. 2d 295, 300 (N.D.N.Y. 1998) (stating that, "[a]s an element of subject matter jurisdiction, the issue of standing should be raised by a motion to dismiss for lack of jurisdiction over the subject matter" (quotation omitted)).

B. Plaintiffs' claim that 10 N.Y.C.R.R. § 23.4 violates their rights under 42 U.S.C. § 300aa-26

1. The Supremacy Clause and federal question jurisdiction

It is well-established that, pursuant to the Supremacy Clause of the United States Constitution, courts "must not give effect to state laws that conflict with federal laws." *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1383 (2015) (citation omitted). "It is equally apparent that the Supremacy Clause is not the "source of any federal rights" . . . and certainly does not create a cause of action." *Id.* (internal quotation omitted). Thus, although "[i]t instructs courts what to do when state and federal law clash, . . . [it] is silent regarding who may enforce federal laws in court, and in what circumstances they may do so." *Id.* Nonetheless, the Supreme Court has held that it is "beyond dispute that federal courts have jurisdiction over suits to enjoin state officials from interfering with federal rights." *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 n.14 (1983) (citation omitted). Additionally, "[a] plaintiff who seeks injunctive relief from state regulation on the ground that such regulation is pre-empted by a federal statute which, by virtue of the Supremacy Clause of the Constitution, must prevail, thus presents a federal question which the federal courts have jurisdiction under 28 U.S.C. § 1331 to resolve." *Id.* (citations omitted); *see also Friends of E. Hampton Airport, Inc. v. Town of E. Hampton*, 841 F.3d 133, 144 (2d Cir. 2016) (finding that the court had "federal equity jurisdiction" over the plaintiffs' claims which sought to enjoin enforcement of a local law on grounds that it violated federal law, as "the Supreme Court has consistently recognized federal jurisdiction over declaratory- and injunctive-relief actions to prohibit the enforcement of state . . . orders alleged to violate federal law" (collecting cases)).

Plaintiffs claim that § 23.4 violates their rights under § 300aa-26 and request that the Court declare that § 23.4 violates § 300aa-26 and enjoin Defendant from enforcing § 23.4. In other

words, Plaintiffs seek declaratory and prospective injunctive relief to prohibit enforcement of a state regulation that they claim is pre-empted by federal law. Although Plaintiffs do not mention the Supremacy Clause by name in their complaint, their characterization of their injury, *i.e.*, that § 23.4 deprives them of the right to receive an "HPV vaccine VIS" under federal law prior to their children receiving the HPV vaccine clearly indicates that the gravamen of Plaintiffs' claim is that § 300aa-26 pre-empts § 23.4. *See* Complaint at ¶ 51 ("to the extent that . . . § 23.4 permits children to be injected with [the HPV vaccine] without parental consent or knowledge, it deprives Plaintiffs and others similarly situated of their right pursuant to 42 U.S.C. § 300aa-26 to receive [the "HPV vaccine VIS"] from the health care provider that intends to inject their children with [the HPV vaccine], along with appropriate additional information regarding those vaccines, before that health care provider performs the injection"). Furthermore, although the court may not assert claims on behalf of the parties before it, "[w]hen a requirement goes to subject-matter jurisdiction, courts are obligated to consider *sua sponte* issues that the parties have disclaimed or have not presented." *Gonzalez v. Thaler*, 565 U.S. 134, 141 (2012) (citation omitted).

For all these reasons, the Court concludes that Plaintiffs have presented a federal question over which this Court has subject matter jurisdiction under 28 U.S.C. § 1331 to resolve. This conclusion, however, does not end the Court's inquiry. Although the presence of federal question jurisdiction confers jurisdiction to entertain a plaintiff's claim, courts must also independently evaluate whether the particular plaintiff has standing to bring such a claim. If a court finds that a plaintiff lacks standing to assert that claim, the court may not properly adjudicate that claim irrespective of the fact that the claim presents a federal question. *See Plante v. Dake*, 621 F. App'x 67, 68 (2d Cir. 2015) (summary order) (stating that, "although the Court erred in ruling that it

lacked federal-question jurisdiction over [the plaintiff's] MSP claims, the Court nonetheless properly dismissed [the plaintiff's complaint] for lack of subject-matter jurisdiction because [the plaintiff] lacked Article III standing to bring the MSP claims"); *Koziol v. Hanna*, 107 F. Supp. 2d 170, 175-76 (N.D.N.Y. 2000) (stating that a court must have both "the statutory and constitutional power to adjudicate" a claim and a plaintiff "must also have standing for a court to exercise subject matter jurisdiction" over that claim (citations omitted)); *see also Tasini v. N.Y. Times, Co., Inc.*, 184 F. Supp. 2d 350, 358 (S.D.N.Y. 2002) (dismissing the plaintiff's complaint because, "even [though the plaintiff] had standing to bring [the] action, his complaint set[] forth no basis for federal jurisdiction" and thus required dismissal pursuant to Rule 12(b)(1)). In other words, notwithstanding the presence of federal question jurisdiction, a court may still be deprived of subject matter jurisdiction over an action if the plaintiff cannot satisfy Article III standing requirements. Thus, the next step in the Court's subject matter jurisdiction analysis is to determine whether Plaintiffs have standing to assert their claims.

2. Standing

Under Article III of the Constitution, federal courts may only decide "actual cases and controversies." *Lee v. Bd. of Governors of Fed. Reserve Sys.*, 118 F.3d 905, 910 (2d Cir. 1997) (citation omitted). Thus, "[t]he Supreme Court has recognized that a litigant's stake in the controversy must extend beyond mere interest in a dispute, and the doctrine of standing has developed to ensure the presence of 'that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends.'" *Id.* (quoting *Baker v. Carr*, 369 U.S. 186, 204, 82 S. Ct. 691, 703, 7 L. Ed. 2d 663 (1962)). The plaintiff bears the burden of proving standing. *See id.*

(citation omitted).

To establish constitutional standing, a plaintiff must prove three things: (1) that she suffered "an injury in fact"; (2) a "causal connection between the injury and the conduct complained of"; and (3) "that it [is] likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Wademan*, 13 F. Supp. 2d at 301 (quotation omitted). "[A]t the pleading stage, standing allegations need not be crafted with precise detail, nor must the plaintiff prove h[er] allegations of injury." *Baur v. Veneman*, 352 F.3d 625, 631 (2d Cir. 2003) (citing [*Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)] (recognizing that, "[a]t the pleading stage, general factual allegations of injury . . . may suffice [to establish standing], for on a motion to dismiss [the court] 'presum[es] that general allegations embrace those specific facts that are necessary to support the claim'" (quotation omitted))). Courts must simply determine "whether the 'Pleading 'allege[s] facts that affirmatively and plausibly suggest that [the plaintiff] has standing to sue.'" *Carter v. Healthport Techs., LLC*, 822 F.3d 47, 56 (2d Cir. 2016) (quoting [*Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 145 (2d Cir. 2011)]) (other citation omitted).

In this case, Defendant claims that Plaintiffs cannot establish the first element of standing, *i.e.*, that they have suffered an "injury in fact."² To satisfy the "injury in fact" requirement of the standing inquiry, a plaintiff must show that her injury is a "legally protected interest" which is both (1) "concrete and particularized" and (2) "actual, or imminent, not "conjectural" or "hypothetical."" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (citations and quotations omitted). Additionally, "[i]mpairments to constitutional rights are generally deemed adequate to support a

² Defendant does not address the causality and redressability requirements of Constitutional standing.

finding of "injury" for purposes of standing." *Fishman v. Daines*, 247 F. Supp. 3d 238, 248 (E.D.N.Y. 2017) (quoting *Doe v. Sch. Bd. of Ouachita Parish*, 274 F.3d 289, 292 (5th Cir. 2001), accord *Council of Ins. Agents & Brokers v. Molasky-Arman*, 522 F.3d 925, 931 (9th Cir. 2008)).

Turning to the first injury-in-fact prong, the court must assess whether an injury is "particularized," *i.e.*, whether the injury "affect[s] the plaintiff in a personal and individual way." *LaFleur v. Whitman*, 300 F.3d 256, 269 (2d Cir. 2002) (quotation omitted). With respect to the particularity requirement, "[t]he fact that an injury may be suffered by a large number of people does not of itself make that injury a nonjusticiable generalized grievance." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 n.7 (2016). Next, the court must determine if the complained-of-injury is "concrete," *i.e.*, the plaintiff alleges an injury that is not too abstract and is "capable of, or otherwise suitable for, judicial resolution." *Bauer v. Veneman*, 352 F.3d 625, 632 (2d Cir. 2003) (citing *Raines*, 521 U.S. at 819, 117 S. Ct. 2312). "Concrete" does not necessarily mean "tangible"; rather, "intangible harms," such as the "risk of real harm," can, in some circumstances, satisfy the "concreteness" requirement. *Spokeo*, 136 S. Ct. at 1549 (citation omitted) (noting that "the law has long permitted recovery by certain tort victims even if their harms may be difficult to prove or measure" (citation omitted)).

With regard to the "actual" or "imminent" requirement of the injury-in-fact inquiry, courts have noted that, although "'imminence' is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes[.]" *Lujan*, 504 U.S. at 564 n.2 (quotation omitted). Thus, a plaintiff who challenges a statute "must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation and enforcement." *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S.

289, 298 (1979) (citation omitted). Although the plaintiff "does not have to await the consummation of threatened injury to obtain preventive relief," *id.* (quotation omitted), "[a]llegations of possible future injury do not satisfy the requirements of Article III," *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990); *see also O'Shea v. Littleton*, 414 U.S. 488, 497 (1974) (finding that the plaintiffs' allegations were too speculative to constitute injury in fact, as they amounted to a claim "that *if* [the plaintiffs] proceed to violate an unchallenged law and *if* they are charged, held to answer, and tried in any proceedings before [the defendants], they will be subjected to . . . discriminatory practices that [the defendants] are alleged to have followed" (emphasis added)). Rather, the plaintiff must demonstrate that "he 'has sustained or is immediately in danger of sustaining some direct injury[.]'" *Young v. N.Y.C. Transit Auth.*, 903 F.2d 146, 162 (2d Cir. 1990) (quotation omitted); *see also Lujan*, 504 U.S. at 564 n.2 (finding that the elastic "imminence" requirement "has been stretched beyond [its] breaking point when . . . the plaintiff alleges only an injury at some indefinite future time"); *Pennell v. City of San Jose*, 485 U.S. 1, 7 (1988) (holding that an association of landlords seeking to enjoin the enforcement of an ordinance empowering a hearing officer to cap the amount of a landlord's rent increase had established a "sufficient threat of actual injury" based on "[t]he likelihood of enforcement, with the concomitant probability that a landlord's rent will be reduced below what he or she would otherwise be able to obtain in the absence of the Ordinance").

Moreover, in cases where a plaintiff seeks "prospective injunctive relief, [she] must allege a 'real and immediate' threat of future violations of [her] rights" to establish injury-in-fact. *Scherr v. Marriott Int'l, Inc.*, 703 F.3d 1069, 1074 (7th Cir. 2013) (citing *City of Los Angeles v. Lyons*, 461 U.S. 95, 102, 103 S. Ct. 1660, 75 L. Ed. 2d 675 (1983)); *see also Frame v. City of Arlington*, 657

F.3d 215, 235 (5th Cir. 2011) (finding that the disabled plaintiffs had standing to claim violations of the Americans with Disabilities Act by the city's maintenance and construction of inaccessible sidewalks, but only as to those sidewalks for which they could demonstrate there was a "sufficiently high degree of likelihood that [they would] be denied the benefits of that sidewalk once it [was] built" (footnote omitted)). "Immediacy" in the standing context "means reasonably fixed and specific in time and not too far off." *Am. Civil Liberties Union of Fla, Inc. v. Miami-Dade Cty. Sch. Bd.*, 557 F.3d 1177, 1193-94 (11th Cir. 2009). Allegations that an injury might occur "some day . . . without any description of concrete plans, or . . . any specification of when the some day will be – do not support a finding of . . . "actual or imminent" injury" *Id.* at 1191 (quotation omitted).

In *Am. Civil Liberties Union of Fla., Inc.*, the Eleventh Circuit found that some of the plaintiffs lacked standing to assert their claims because they had not demonstrated that their injury was "imminent." *Am. Civil Liberties Union of Fla., Inc.*, 557 F.3d at 1197. In that case, the plaintiffs only alleged that they wished, at some point in the future, to check out certain library books at issue but did not indicate "some fixed period of time in the reasonably foreseeable future during which they want[ed] to use the books." *Id.* The court noted that standing requires "specification, not imagination" and that, "[w]ithout embellishment," the plaintiffs had not met their burden to show that they faced a threat of imminent injury from the removal of the books at issue. *Id.*

In this case, Plaintiffs assert that § 23.4 has injured them in two ways: (1) by depriving them of their constitutional right "to make decisions concerning the care, custody and control of their children" and (2) by depriving them of their federal statutory right pursuant to § 300aa-26 of the NCVIA to receive an "HPV vaccine VIS" prior to their children's receipt of the HPV vaccine. As to

their first alleged injury, it is well-recognized that "[i]mpairments to constitutional rights are generally deemed adequate to support a finding of 'injury' for purposes of standing." *Fishman*, 247 F. Supp. 3d at 248 (quotation omitted). Thus Plaintiffs' alleged constitutional-related injury is adequate for purposes of standing. Furthermore, Plaintiffs' second alleged injury is also a cognizable injury in fact, as "the violation of a . . . right granted by statute can be sufficient in some circumstances to constitute injury in fact." *Spokeo*, 136 S. Ct. at 1549.

With regard to the issue of "concreteness," Plaintiffs' first alleged injury, *i.e.*, that § 23.4 prevents them from knowing whether their children have received the HPV vaccine and, thus, deprives them of their fundamental right under the Due Process Clause to make informed medical decisions for their children, is not too abstract such that it would be incapable of or unsuitable for judicial resolution. To the contrary, Plaintiffs' claim that § 23.4 directly interferes with their ability to make informed medical decisions on behalf of their minor children is legitimate, as the statute authorizes health care practitioners "to render medical care related to . . . sexually transmitted diseases without the consent or knowledge of [a minor child's] parent" and prohibits health care practitioners from releasing medical records to a parent without the minor patient's permission. *See* 10 N.Y.C.R.R. § 23.4. As Plaintiffs plausibly allege in their complaint, this alleged deprivation could be remedied judicially in the form of declaratory and injunctive relief prohibiting the enforcement of § 23.4. Therefore, the Court finds that Plaintiffs' allegation that § 23.4 injures their constitutional Due Process rights is sufficiently concrete for standing purposes.

Turning to Plaintiffs' second alleged injury, *i.e.*, that § 23.4 deprives them of their right under § 300aa-26 to receive the "HPV vaccine VIS" prior to a health care practitioner injecting their children with the HPV vaccine, it is unclear whether the violation of this federal *procedural* right is

sufficiently concrete to satisfy the injury-in-fact requirement. That is, although in some circumstances a plaintiff may satisfy the concreteness requirement by alleging that the violation of a statutorily guaranteed procedural right presents a "risk of harm," *see, e.g., Fed. Elec. Comm'n v. Atkins*, 524 U.S. 11, 21 (1988) (finding that the plaintiffs' "inability to obtain information" pursuant to their rights under the Federal Election Campaign Act was sufficient to satisfy the injury in fact requirement); *Pub. Citizen v. United States Dep't of Justice*, 491 U.S. 440, 449 (1989) (holding that the plaintiffs' inability to obtain information subject to disclosure guaranteed under the Federal Advisory Committee Act "constitute[d] a sufficiently distinct injury to provide standing to sue"), the Supreme Court has generally concluded that "bare procedural violation[s], divorced from any concrete harm," do not satisfy the injury-in-fact requirement, *Spokeo*, 136 S. Ct. at 1549.

Accepting Plaintiff's allegations as true, a failure to comply with the pre-vaccination procedural requirements of § 300aa-26 could do more than deprive Plaintiffs of their right to receive an "HPV vaccine VIS" prior to a health care practitioner administering the vaccine to their children. Rather, it could in fact directly interfere with Plaintiffs' constitutional right to make informed medical decisions for their children because § 23.4 could ultimately deprive them of the ability to guide and assist their children with respect to their decision whether to receive the vaccine. For example, without receiving the "HPV vaccine VIS," Plaintiffs could not counsel their children about any adverse reactions they might experience after its administration; and, they claim, their children lack the maturity and wherewithal to make such important and potentially dangerous health-related decisions on their own. Thus, the Court finds that Plaintiffs have alleged a "concrete" injury because failure to receive the "HPV vaccine VIS" could directly interfere with Plaintiffs' Due Process right to make decisions regarding the care and custody of their children.

Additionally, the injuries in this case are "particularized." Plaintiffs are all parents of minor children who are eligible to receive the HPV vaccine and who may do so without their parents' permission under § 23.4. *See* Complaint at ¶ 8. In fact, Plaintiff Meyer claims that her daughter has already received the HPV vaccine and was "severely injured" as a result. She is concerned that, if her daughter, unaware that she had already received the HPV vaccine, were to make an appointment with a health care practitioner and request that he or she inoculate her with the HPV vaccine, without her mother's knowledge, she could suffer a similar serious injury. The other Plaintiffs' children apparently have not yet been administered the HPV vaccine; and, thus, their concern is that their children, who are not mature enough to make an informed decision or to recognize the side effects of the HPV vaccine, could request that a health care practitioner administer the vaccine without their parents' consent and could be seriously injured as a result. Thus, the Court concludes that the complained-of injuries are sufficiently particularized because they affect each Plaintiff "personally" and in an "individual" way. Moreover, the fact that many parents in New York State may have minor children who could also receive the HPV vaccine without their parents' knowledge and consent pursuant to § 23.4 does not make Plaintiffs' alleged injuries "nonjusticiable," as the Supreme Court has indicated that "[t]he fact that an injury may be suffered by a large group of people" does not convert the injury into a "generalized grievance," *Spokeo*, 136 S. Ct. at 1548 n.7.

However, Plaintiffs have not met the second injury-in-fact prong, *i.e.*, whether the alleged injuries are "actual" or "imminent" as opposed to "conjectural" or "hypothetical." For example, much like the "if this . . . then that" characterization of the plaintiffs' alleged injury in *O'Shea*, the potential injuries Plaintiffs allege also amount to various iterations of "if this . . . then that" and are simply too speculative to meet the imminence prong. That is, *if* Plaintiffs' children received the

HPV vaccine without their parents' consent, and *if* they do not give their health care practitioners consent to release that information to their parents or *if* the children do not disclose this information to their parents themselves, and *if* Plaintiffs decide to have their children receive the HPV vaccine at some unspecified point in the future, unaware that their children have already received the HPV vaccine, a further injection would "expose the child to the risk of adverse reactions." As a result, Plaintiffs claim that this "uncertainty" injures them because it deprives them of the ability to make informed medical decisions such as whether their children should receive the HPV vaccine.

Plaintiffs' allegations of "possible" future injury require "imagination" or "embellishment" on the part of the Court that Plaintiffs' children, ages 11, 13, 15 and 16, may attempt to receive the HPV vaccine without their parents' permission and may decline to give permission to their health care practitioners to release that information to their parents. However as the court pointed out in *Am. Civ. Liberties Union of Fla., Inc.*, courts may not "embellish" and "imagine" a standing-conferring scenario for a plaintiff in which the alleged injury might occur if the plaintiff does not plead her case with the requisite specificity to demonstrate that her injury is indeed actual and imminent. More importantly, however, the scenarios the Court must envision in this case for any potential injury to occur are simply not plausible. That is, the Court must imagine a situation in which there is a real risk that Plaintiffs' children will receive the HPV vaccine multiple times, which, under the circumstances, is not likely and is certainly not imminent.

Moreover, assuming that Plaintiffs had indicated that they intended to have their children receive the HPV vaccine or that their children expressed a wish to receive the vaccine themselves, which, as previously discussed, does not seem to be the case, the Court must then assume that Plaintiffs' children, all of whom but one, is not old enough to drive, somehow went to the office of a

health care practitioner, other than the health care practitioner to whom their parents usually took them without their parents' knowledge, received the HPV vaccine from that practitioner, did not give the practitioner permission to share the information that they had received the HPV vaccine with their parents, and then their parents take them to a different health care practitioner who inoculates them with the HPV vaccine for a second time and that, as a result, they suffer an adverse reaction to the vaccine.³ Accordingly, the Court concludes that, even if it were permitted to engage in such embellishments or exercise of imagination, which it is not, such hypothetical, standing-conferring scenarios in which Plaintiffs' alleged injuries would occur are simply not plausible.

Furthermore, Plaintiffs' allegations that they could suffer injury at some point in the future, without specifying "when that some day will be" or that their children have received or intend to receive the HPV vaccine simply do not plausibly suggest that there is a "real and immediate" threat of injury to Plaintiffs' rights as required to establish standing in an action seeking prospective injunctive relief. *See, e.g., Babbitt*, 442 U.S. at 298 (noting that, although a plaintiff need not "await the consummation of a threatened injury to obtain preventive relief," she nonetheless must demonstrate that the injury is "certainly impending" to demonstrate injury-in-fact (citations and

³ Adding to the implausibility of this scenario is the fact that, in New York, a health care practitioner must consult New York's electronic immunization information system to view a child's immunization history, including whether a child has received the HPV vaccine, prior to immunizing a child: "[t]he [system] . . . shall serve as a means for authorized users[, including health care practitioners,] to receive prompt and accurate information . . . about the vaccines that the registrant has received." N.Y. Pub. Health Law § 2168(3)(c). Moreover, any health care practitioner who administers a vaccine must report the immunization to the system and, in the case of a minor, does not need the consent of the minor to report such immunization. *See* N.Y. Pub. Health Law § 21168(3)(a)(i). Therefore, it seems implausible if not inconceivable, that a health care provider would be at risk of administering the HPV vaccine to a minor who had previously been inoculated with the HPV vaccine or would knowingly administer a second HPV vaccine to a minor who had already received said vaccine.

quotations omitted)).

For all these reasons, the Court finds that Plaintiffs have not satisfied the "injury-in-fact" requirement of standing because they have not alleged injuries that are "actual" or "imminent"; and, therefore, Plaintiffs lack standing to assert these claims.

IV. CONCLUSION

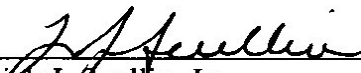
Having reviewed the entire file in this matter, the parties' submissions, and the applicable law, and for the above-stated reasons, the Court hereby

ORDERS that Defendant's motion to dismiss Plaintiffs' complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, *see* Dkt. No. 8, is **GRANTED**; and the Court further

ORDERS that the Clerk of the Court shall enter judgment in Defendant's favor and close this case.

IT IS SO ORDERED.

Dated: February 28, 2019
Syracuse, New York



Frederick J. Scullin, Jr.
Senior United States District Judge